

NIH Global Health Interest Group, Seminar Series

January 16, 2013

Seminar Title: PATH's Comprehensive Approach to R&D in the Developing World

Presenter: Jorge Flores, Director, Clinical & Regulatory Affairs, PATH

In his seminar Jorge gave a broad introduction to PATH's work around the world whose overall mission is to "improve the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors". Their objective is accomplished by applying entrepreneurial and innovative approaches that ensure "health is within reach for everyone".

PATH's focus areas include (1) Health Technologies, e.g. vaccines, diagnostics, water purification. (2) Vaccines & Immunization for malaria, meningitis, pneumococcal, rotavirus, etc. (3) Maternal & Child Health, e.g. diarrhea prevention, child nutrition, safe birthing practices. (4) Reproductive Health issues including family planning, reproductive health supplies and cervical cancer prevention and (5) Emerging & Epidemic diseases, e.g. HIV/AIDS, malaria, tuberculosis, influenza. PATH's work spans the globe but is focused on African countries and India as these regions experience the highest death rates from infectious and parasitic diseases but devote relatively little in R&D towards prevention and cures.

PATH is unique in that it works by establishing and managing partnerships that align with their goals. PATH identifies candidates and utilizes their own financial resources, technical expertise and forms partnerships to accelerate the development of lifesaving technologies against major disease threats in the developing world. To do this, PATH leverages its partners from industry, academia, NGO's and various government agencies in order to implement direct R&D, manufacturing, and distribution of novel technologies. Through these collaborations PATH hopes to improve global availability, accessibility and affordability of these technologies. This in part is accomplished by negotiating terms with partners to make sure vaccines are affordable, there is dedicated manufacturing capacity, and that the vaccines meet WHO and FDA quality standards and requirements. In essence, through their innovative partnering approach PATH seeks to change the risk-return relationship of vaccine R&D for the developing world thus making it an attractive endeavor for the private sector.

A significant portion of PATH's overall efforts are concerned with vaccines and immunization which encompasses not just R&D but also advocacy, financing, distribution, administration and uptake. Jorge stressed that many vaccines are not available or are not affordable for vast numbers of people living in the developing world. As a result, each year 1.5 million children die from vaccine-preventable diseases. As an example, Jorge presented an update on PATH's malaria vaccine initiative (MVI). Even though malaria is almost absent in the developed world, each year 350-500 million cases of malaria occur worldwide. In sub-Saharan Africa over 1 million people die each year and in 2002 malaria was the fourth leading cause of death in children in developing countries. The goal of the MVI is to develop a vaccine for infants and young children primarily living in sub-Saharan Africa. In 2001 PATH partnered with GlaxoSmithKline to begin clinical trials of the previously-developed malaria vaccine RTS,S. Approximately 16,000 children were enrolled in clinical trials in 11 study sites spread across 7 African countries. Current results from the RTS,S trials are promising: after 12 months of follow-up, vaccination with RTS,S led to a reduction in the incidence of a malaria (vaccine

efficacy) of 55.8% among children 5 to 17 months of age and among children 6 to 12 weeks of age vaccine efficacy was 30.1%.

In addition to the malaria initiative, PATH also works on developing vaccines to eliminate meningitis epidemics throughout Africa and to prevent diarrheal diseases caused by rotavirus, Shigella and enterotoxigenic E. Coli. Each project is different and presents unique constraints and challenges but PATH's innovative approach appears well-suited and so far, highly successful.

In conclusion, Jorge stressed that vaccines are still one of the most successful and cost-effective public health interventions available today. Because many vaccines are not affordable or are unavailable millions of children remain unimmunized. To close the immunization gap PATH continues to work through their ongoing partnerships to ensure greater health-access to those populations living in the developing world.